

VEECH, Richard L.
Appl. No. 10/734,586
June 19, 2007

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REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 1-18 are in the case.

I. SPECIFICATION

A new Abstract is presented on a separate sheet attached hereto. The Abstract is based on claim 8. No new matter is entered.

II. THE 35 U.S.C. 112, SECOND PARAGRAPH, REJECTION

Claims 8-10 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for the reasons stated on page 3 of the Action. In response, and without conceding to the merit of the rejection, claim 8 has been amended to incorporate the blood levels of (R)-3-hydroxybutyrate at 0.5 to 20mM as recited in paragraph [0067] of the present application as published. No new matter is entered. Withdrawal of the rejection is respectfully requested.

III. THE OBVIOUSNESS REJECTION

Claims 8-10 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over U.S. patent 6,380,244 to Martin et al. That rejection is respectfully traversed.

The claimed invention provides a method of producing a physiologically acceptable ketosis such as to treat a patient in need of therapy for one or more of Amyotrophic lateral sclerosis, Free Radical disease, Heart failure and Duchenne's muscular dystrophy. The method comprises oral administration to the patient of a cyclic oligomer of formula (I) where n is an integer of 1 or more or a complex thereof with one

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or more cations or a salt thereof, wherein the physiologically acceptable ketosis is characterized by blood levels of (R)-3-hydroxybutyrate of from 0.5 to 20 mM.

Martin does not render obvious the invention as now claimed. The dates that various aspects of the invention were incorporated are set out in the attached table.

Martin	Present application
<p>From filing 22.July.1998: Seizure control, metabolic disease control, reduction in protein catabolism, appetite suppression and parenteral nutrition</p>	<p>From filing 15.September.1998: Neurodegenerative diseases, neurotoxic effects of pathogenic agents such as protein plaques and oxidative damage. Disease states mediated by free radicals, toxic agents such as peptides and proteins, genetic defects such as Leigh's syndrome, insulin resistance, glucose metabolism defects or defect inducing states, ischemia, for increasing cell efficiency, heart cell efficiency. Seizure related disorders such as refractory epilepsy. Neuronal stimulation, stimulation of axonal and/or dendritic growth of nerve cells e.g., hippocampal and substantia nigra cells. Free radical damage diseases such as Parkinson's disease, Amyotrophic lateral sclerosis, Alzheimer's disease, cerebral ischemia, coronary reperfusion, diabetic angiopathy, inflammatory bowel disease an pancreatitis. Hypoglycemic brain dysfunction. Body lipid content reduction 15.09.98</p>
<p>From filing 22.July.1999: Increasing cardiac efficiency, treatment of diabetes and insulin resistant states, neurodegenerative disorders and epilepsy. Diseases involving neurotoxic plaques, such as amyloid plaques: Alzheimer's disease, fronto-temporal degeneration associated with Pick's disease, vascular dementia, senile dementia, senile dementia of Lewy body</p>	<p>From filing 15.September.1999 Head trauma. Production of physiologically acceptable ketosis. Increased efficiency of mitochondrial energy production in humans/animals not suffering from metabolic disease. Type II diabetes, deficiency or blockage of pyruvate dehydrogenase, Duchene's muscular dystrophy.</p>

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type, dementia of Parkinsonism with frontal atrophy, progressive supranuclear palsy and corticobasal degeneration, Downs syndrome associated with Alzheimer's, myasthenia gravis and muscular dystrophy. Improvement of nerve cell function and growth and enhanced cellular energy production.
22.07.99

The invention as now claimed is directed to treating patients suffering from one or more of Amyotrophic lateral sclerosis, Free Radical disease, Heart Failure and Duchenne's muscular dystrophy. None of these conditions is suggested by the Martin filings. One of ordinary skill would not, therefore, have been motivated to arrive at the present invention based on the Martin disclosures. Withdrawal of the obviousness rejection is accordingly respectfully requested.

IV. DOUBLE PATENTING

Claims 8-10 stand rejected on obviousness-type double patenting grounds as allegedly unpatentable over claims 1-19 of U.S. patent 6,323,237. With the claim amendments presented herewith, it is believed that the invention as now claimed in the present application is not suggested by the claims of the '237 patent. The obviousness-type double patenting rejection should therefore be withdrawn. Such action is respectfully requested.

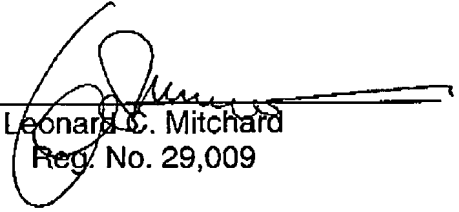
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Favorable action is awaited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____


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